Appl. No.: 10/552,957 Amdt. dated 09/20/2010

Reply to Office action of 05/11/2010

## Amendments to the Claims:

1. (Currently Amended) An immunomodulatory product obtained according to a method of preparation comprising the following steps:

- inoculation and incubation, under aerobic or anaerobic conditions and at a temperature of between approximately 30 and 40°C, of *Bifidobacterium* comprising at least the strain *Bifidobacterium breve* strain deposited under the number I-2219 with the CNCM (Collection Nationale de Cultures de Microorganisms in Paris, France) in an aqueous substrate having a pH of between approximately 6 and 8 and comprising at least the following ingredients:
  - i) lactoserum permeate,
  - ii) a lactoserum protein hydrolyzate,
  - iii) lactose,
  - removal of the *Bifidobacterium* from the aqueous substrate;
- ultrafiltration of the aqueous substrate through filtration membranes having a cutoff threshold of between 100 and 300 kDa, so as to obtain a concentrated retentate;
  - dehydration of the concentrated retentate,
  - dissolution of the dehydrated retentate in a buffer;
- gel exclusion chromatography of the retentate solution, on a column having an exclusion threshold of 600 kDa:
- recovery of the excluded fraction at the end of the chromatography, which fraction constitutes the immunomodulatory product.
- 2. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the *Bifidobacterium* bacteria are inoculated into the aqueous substrate in a proportion of  $1 \times 10^4$  to  $4 \times 10^9$  colony forming units per ml of substrate.
- 3. (Previously Presented) The immunomodulatory product as claimed in claim 1 wherein the temperature of the substrate is maintained at a value of between 37 and 40°C throughout the incubation period.
- 4. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the pH of the aqueous substrate is maintained at a value of between 6 and 8 throughout the incubation period.

Appl. No.: 10/552,957 Amdt. dated 09/20/2010 Reply to Office action of 05/11/2010

- 5. (Previously Presented) The immunomodulatory product as claimed in claim 4, wherein the pH of the aqueous substrate is maintained at a value of between 6.5 and 7.5 throughout the incubation period.
- 6. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the ingredients of the aqueous substrate are present in the following amounts:
  - i) lactoserum permeate: from 3 to 80 g,
  - ii) lactoserum protein hydrolyzate: from 2 to 80 g,
- iii) lactose: from 5 to 50 g, these amounts being given per liter of said aqueous substrate.
- 7. (Previously Presented) The immunomodulatory product as claimed in claim 6, wherein the ingredients of the aqueous substrate are present in the following amounts:
  - i) lactoserum permeate: from 40 to 60 g,
  - ii) lactoserum protein hydrolyzate: from 5 to 15 g,
- iii) lactose: from 10 to 30 g, these amounts being given per liter of said aqueous substrate.
- 8. (Currently Amended) The immunomodulatory product as claimed in claim 1, wherein the aqueous substrate also comprises at least one additional ingredient selected from the group consisting of chosen from buffer salts, yeast extracts and cysteine hydrochloride.
- 9. (Currently Amended) The immunomodulatory product as claimed in claim 8, wherein the aqueous substrate comprises a buffer salt selected from the group consisting of ehosen from sodium dihydrogen phosphate and potassium dihydrogen phosphate, which represents from 0.5 to 5 g per liter of aqueous substrate.
- 10. (Previously Presented) The immunomodulatory product as claimed in claim 8, wherein the yeast extract represents from 0.5 to 5 g per liter of aqueous substrate.
- 11. (Previously Presented) The immunomodulatory product as claimed in claim 8, wherein the cysteine hydrochloride represents from 100 to 500 mg per liter of aqueous substrate.
  - 12. (Previously Presented) The immunomodulatory product as claimed in claim 1,

Appl. No.: 10/552,957 Amdt. dated 09/20/2010

Reply to Office action of 05/11/2010

wherein the removal of the *Bifidobacterium* from the culture medium is carried out by microfiltration or by centrifugation of the aqueous substrate.

- 13. (Previously Presented) The immunomodulatory product as claimed in claim 12, wherein the removal of the *Bifidobacterium* from the culture medium is carried out by centrifugation of the aqueous substrate.
- 14. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the method also comprises, after the *Bifidobacterium* removal step, an additional step consisting of destruction of the residual enzymatic activities contained in the aqueous substrate after incubation.
- 15. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the exclusion chromatography is carried out on a crosslinked agarose and dextran gel.
- 16. (Previously Presented) The immunomodulatory product as claimed in claim 1, wherein the excluded fraction essentially consists of a complex of polysaccharides and of proteins in which the carbohydrate fraction represents from 5 to 30% by weight, the protein fraction representing from 70 to 95% by weight relative to the total weight of said complex.
- 17. (Previously Presented) The immunomodulatory product as claimed in claim 16, wherein the carbohydrate fraction of the excluded fraction has the following monosaccharide composition (expressed as molar ratios with respect to rhamnose): galactose: 5.5 to 8; mannose: 0.8 to 1.3; glucose: 2.5 to 5; N-acetylgalactosamine: 0.3 to 1; N-acetylglucosamine: 0.07 to 0.3; neuraminic acid: 0 to 0.15, and rhamnose: 1.
- 18. (Previously Presented) The immunomodulatory product as claimed in claim 16, wherein the protein fraction comprises at least one peptide corresponding to at least one of the following sequences:
  - RELGIGTPSFLHNGGQWYIYA (SEQ ID No. 1)
  - RVLYNPGQYXYVR (SEQ ID No. 2)
  - EQATANGQVSSGQQSTGGSAAP (SEQ ID No. 3).
  - 19. (Previously Presented) A medicament comprising the immunomodulatory

Appl. No.: 10/552,957 Amdt. dated 09/20/2010

Reply to Office action of 05/11/2010

product as claimed in claim 1.

- 20. (Previously Presented) An immunomodulatory medicament comprising the immunomodulatory product as claimed in claim 1.
- 21. (Previously Presented) A pharmaceutical composition, containing, as active principle, at least one immunomodulatory product obtained according to the method as defined in claim 1, and at least one pharmaceutically acceptable carrier.
- 22. (Previously Presented) The pharmaceutical composition as claimed in claim 21, wherein it is intended for oral administration and in that it is in the form of a liquid or of a solid.
- 23. (Previously Presented) A food composition, containing, as an ingredient, at least one immunomodulatory product obtained according to the method as defined in claim 1.
- 24. (Currently Amended) The food composition as claimed in claim 23, wherein [[it]] the composition is in the a form of a fermented or non-fermented, milk or non-milk preparation, of animal or plant origin, including infant formulas, or for adults or senior citizens.
- 25. (Currently Amended) The food composition as claimed in claim 24, wherein [[it]] the composition is in the <u>a</u> form of liquid or powdered milk, of fresh products, of cereals, of biscuits, of jars of baby food, of desserts, of products for hospitals, of dietetic products or of nutritional supplements.